James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
Telephone: 602.382.6000
Facsimile: 602.382.6070
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Facsimile: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' NOTICE OF SUPPLEMENTAL INFORMATION REGARDING FDA INSPECTION AND WARNING LETTER

Defendants C. R. Bard, Inc. ("C. R. Bard") and Bard Peripheral Vascular, Inc. ("BPV") (C. R. Bard and BPV are collectively referred to as "Bard") hereby give notice of supplemental information (received within the past week) regarding the FDA inspection and Warning Letter. Specifically, the FDA has just recently issued two Form 483 Letters,[1] one directed to Bard's IVC filter manufacturing facility, Glens Falls

[1] An FDA Form 483 Letter is a notification from the FDA to a medical device manufacturer that documents observations by an inspector that certain conditions observed during an inspection may constitute violations of the Food Drug & Cosmetic Act or related Acts or FDA regulations. An FDA Form 483 Letter <u>*is not*</u> a final FDA determination that an alleged violation has occurred. *See* FDA's Form 483 Frequently Asked Questions, available at http://www.fda.gov/ICECI/Inspections/ucm256377.htm.

Operations ("GFO"), and one directed to BPV, following FDA inspections at those facilities in February 2016. *See* Form 483 Letters attached as Exhibit "A." As with FDA's inspection and Warning Letter, these Form 483 Letters have little, if any, relevance to the issues at stake in the Bard IVC Filter Litigation. Indeed, these Form 483 Letters do not impact or alter Bard's argument that it has provided Plaintiffs with substantial discovery regarding the Warning Letter, and that significant additional discovery regarding the Warning Letter (or these Form 483 Letters) is unwarranted. *See* Bard's Memorandum Regarding the Warning Letter [Dkt. No. 693].

The FDA's Form 483 Letter to GFO concerns certain IVC filter cleanliness inspections performed in March 2015. The FDA alleges that Bard's internal protocol required that inspections be performed three times but that Bard inspected them two times. Bard has reported to the FDA that it has corrected the alleged deficiency, although FDA has not yet verified the correction in a follow-up inspection. Nothing in the Letter suggests that the alleged deficiency impacts the integrity of Bard's IVC filters or otherwise impacts Plaintiffs' manufacturing defect claims. In short, the Form 483 Letter to GFO has no impact on this litigation.

Likewise, the Form 483 Letter to BPV has little impact on this litigation and the arguments made by Bard in its Memorandum Regarding the Warning Letter [Dkt. No. 693]. The Letter to BPV concerns Bard's written procedure for comparing complaint rates month-to-month. It asserts that for products that are no longer on the market, the procedure does not provide for documented methods to conduct "early detection" trending when comparing complaint rates month-to-month, because Bard's early detection system is based on monthly sales.

While the FDA's Form 483 Letter to BPV addresses Bard's written procedure for complaint ***trending***, it does not criticize or otherwise call into question Bard's methods for computing its internal complaint ***rates*** for IVC filters. In this litigation, where Plaintiffs allege that Bard's IVC filter complaint rates are comparatively higher than competitors, and that Bard had a duty warn about such comparative rates, whether Bard's methods for

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

computing its internal rates are adequate is most important, not whether Bard has a written procedure adequately designed to document monthly changes in complaint trends for products that are no longer marketed.[2] Therefore, at most, the FDA's Form 483 Letter to BPV may warrant a short follow-up 30(b)(6) deposition of Mr. Chad Modra -- who was Bard's witness regarding the Warning Letter and who has been involved with FDA's recent inspections -- regarding the FDA's observations. However, the Letter does not warrant the expansive discovery regarding the FDA inspection or Warning Letter that Plaintiffs have previously demanded.

DATED this 4th day of March, 2016.

SNELL & WILMER L.L.P.

By: s/ *Amanda C. Sheridan*

James R. Condo
Amanda C. Sheridan
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
Nelson Mullins Riley & Scarborough LLP
201 17th Street, NW, Suite 1700
Atlanta, GA 30363

Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000

[2] Bard further notes that it does have numerous tools and methods to conduct complaint trending for products that are no longer marketed, although those tools and methods are not explicitly described in Bard's written procedure for complaint trending.

CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ *Amanda C. Sheridan*

23633156

Snell & Wilmer L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
602.382.6000